



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Terrance C. Coyne, M.D.
• Vice President
Medical, Scientific and Legal Affairs
Medeva Pharmaceuticals, Inc.
P.O. Box 1710
755 Jefferson Road
Rochester, NY 14603

Re: Docket Number 00P-1370/CP1 & PSA1

Dear Dr. Coyne,

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that the we are still considering your Citizen Petition request to change the established name of Zaroxolyn Tablets from "metolazone, tablets, USP" to "metolazone slow-low release tablets" and your related Petition for Stay of Action, requesting that the FDA stay the approval of all ANDAs or NDAs that have been filed or may be filed in the future until the requested name change has been effected.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

00P-1370

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